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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/856,336 | 08/20/2001 | Neil James Butt | 7174555913 | 6843 |
| Z1874 | 7590 | 06/23/2005 | EXAMINER | |
| EDWARDS & ANGELL, LLP P.O. BOX 55874 BOSTON, MA 02205 | | | MARVICH, MARIA | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1636 | |

DATE MAILED: 06/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--|------------------------------------|--|
| Office Action Summary | Application No. 09/856,336 | Applicant(s) BUTT ET AL. | |
| | Examiner Maria B. Marvich, PhD | Art Unit 1636 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 and 37-49 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 13, 14, 34 and 35 is/are allowed.
- 6) ☒ Claim(s) 1, 3-12, 15-33, 37-42 and 45-49 is/are rejected.
- 7) ☒ Claim(s) 43 and 44 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. <u>5/20/05</u> |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

This is a supplemental office action to correct typographical errors in the office action mailed 5/19/05. Claims 2 and 36 have been cancelled. Claims 48-49 have been added. Claims 1, 24, 25, 30, 31, and 37 have been amended. Claims 1, 3-35 and 37-49 are pending.

Response to Amendment

Any rejection of record in the previous action not addressed in this office action is withdrawn. There are no new grounds of rejection herein that were not necessitated by applicants' amendment and therefore, this action is Final.

Priority

Receipt is acknowledged of papers filed under 35 U.S.C. 119 (a)-(d) based on an application filed in the U.K. on 17 November 1998. Applicant has not complied with the requirements of 37 CFR 1.63(c), since the oath, declaration or application data sheet does not acknowledge the filing of any foreign application. A new oath, declaration or application data sheet is required in the body of which the present application should be identified by application number and filing date.

Response to Argument

Applicants' statement that a new oath is forthcoming is acknowledged.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-12, 15-23 and 37-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new rejection necessitated by applicants' amendment.**

The limitation that "most of the plasmid DNA is isolated from the genomic DNA" has been added to the claims. Applicant has not indicated where support for this limitation is found. The examiner has been unable to find literal support in the originally filed specification for the phrase that "most of the plasmid DNA is isolated from the genomic DNA". While the specification teaches that the plasmid DNA is isolated from plasmid DNA containing material, it does not demonstrate that most of the genomic DNA is absent from the sample or that the method results in separation of most of the genomic DNA from the sample. . Therefore, the limitation of adding "" is impermissible NEW MATTER.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

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Claims 24-33 and 45-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 48-49 are vague and indefinite in that the metes and bounds of the word “substantially” are unclear. The term “substantially” is a relative one not defined by the claim, no single set of conditions is recognized by the art as being “substantial” and because the specification does not provide a standard for ascertaining the requisite degree. **This is a new rejection necessitated by applicants’ amendment.**

Claims 24-33 and 45-47 recites the limitation "extraction solution " in said claims. There is insufficient antecedent basis for this limitation in the claim. An extraction solution need not be in a mixture. **This is a new rejection necessitated by applicants’ amendment.**

Response to Amendment

Applicants traverse the claim rejections under 35 U.S.C. 112, second paragraph on pages 10-12 of the amendment filed 1/26/05. Applicants argue that claim language is not required to be limited only to a single set of conditions but can be defined in the dictionary or described in the specification through examples and methods. The instantly recited term “substantially” is defined in the dictionary and described in example 1. In this example, separation conditions were evaluated as “OK”, “Good” and “Poor”. Applicants argue that even for separation conditions that do not result in absolute sequestration of the plasmid DNA in the organic phase, the methods may be of some use. Furthermore, it is argued that the differences between plasmid DNA and genomic DNA can be evaluated on agarose gels, which would enable the practitioner

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of the present invention to observe whether the plasmid DNA was “substantially” in one fraction and genomic DNA in the other. Finally applicants argue that the plasmid DNA and/or genomic DNA need not be 100% in order to fall within the limitations of the claims.

Applicants’ argument filed 1/26/05 has been fully considered but they are not persuasive. The courts have determined that use of terms such as “substantial portion” are indefinite when the specification lacked some standard for measuring the degree intended *Ex parte Oetiker*, 23 USPQ2d 1641. In the instant case, the specification describes extraction mixtures that are able to generate DNA purification that is “good”, 1 µg of DNA, “OK” that is 200 ng and “Poor” which is just visible DNA. However, it is unclear how these values demonstrate the relative amount of plasmid, which has been partitioned into the butanol versus aqueous phase or the separation conditions. Rather these numbers indicate the actual amount of DNA isolated from samples using the instantly recited methods. Therefore, the instant specification lacks any standard for measuring the requisite degree intended for the term “substantially”.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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Claims 24-25, 29-33, 41-42 and 45 are rejected under 35 U.S.C. 102(e) as being anticipated by Colpan et al (US 6,383,393 B1; see entire document). **This rejection is maintained for reasons of record in the office action mailed 7/26/04 and restated below.**

Colpan et al teaches methods for the purification of nucleic acids such as the isolation of plasmid of cosmid DNA from *E. coli* using an aqueous solution (column 2, line 1-10 and line 63-67). As demonstrated in examples 1, plasmid DNA is separated from the genomic DNA given A260/280 ratio and the large quantities of plasmid DNA, it is believed most of the plasmid DNA isolated from the genomic DNA. For the extraction of the DNA, the aqueous solution comprises high concentrations of chaotropic salts used in combination with aliphatic alcohols with a chain length of 1 to 5 carbon atoms (see e.g. column 4, line 66 through column 5, line 5). Specifically recited for use in the aqueous chaotropic solution is butanol (see e.g. column 5, line 20-27). Water is a weak base and is an essential element of the extraction mixture taught by Colpan et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Colpan et al (US 6,383,393 B1; see entire document) in view of Sawadogo and Dyke (NAR, 1991, Vol 19(3),

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page 674; see entire document). **This rejection is maintained for reasons of record in the office action mailed 7/26/04 and restated below.**

Applicants claim an extraction mixture, which comprises butanol, a chaotrope, and water. Butanol is n-butanol, 2-methylpropanol or butan-2-ol.

The teachings of Colpan et al are described above and are applied as before except; Colpan et al do not teach that Butanol is n-butanol, 2-methylpropanol or butan-2-ol.

Sawadogo and Dyke teach the use of n-butanol in the extraction of oligonucleotides (see e.g. column 1, paragraph 3).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the butanol taught by Colpan et al with the n-butanol taught by Sawadogo and Dyke because Colpan et al teach that it is within the ordinary skill of the art to use butanol in an extraction mixture and because Sawadogo and Dyke teach that it is within the ordinary skill of the art to use n-butanol for extraction of DNA. One would have been motivated to do so in order to receive the expected benefit of reduced organic contaminants following use of n-butanol (Sawadogo and Dyke, page 674, column 1, paragraph 3). Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Response to Argument

Applicants traverse the claim rejections under 35 U.S.C. 102 (e) and 103(a) on pages 19-21 of the amendment filed 1/26/05. Applicants argue that the present invention provides an extraction mixture, which can selectively extract plasmid DNA from total DNA with an organic

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solvent that is immiscible with the chemotropic-containing aqueous phase. Applicants state that the claims have been amended to emphasize this point. Applicants continue that in contrast to the instant invention, Colpan et al do not disclose a biphasic extraction mixture but disclose that the butanol is miscible with water within these ranges.

Applicants' arguments filed 1/26/05 have been fully considered but they are not persuasive. Colpan et al teach that within the range of 1 to 50%, butanol is miscible with water. Miscible is defined as combines with water but does not describe the completeness of this process. Therefore, it would be inherent that at some of the concentrations of butanol, some butanol will not enter the water and thus form an organic phase. This is schematically depicted in the figure on page 2 of the document labeled SCHP-445 and described in paragraph 2 of page 1. Three butyl alcohols are only partially soluble in water.

Conclusion

Claims 1, 3-12, 15-33, 37-42 and 45-49 are rejected.

Claims 13, 14, 34 and 35 are allowed.

Claims 43 and 44 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B. Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD can be reached on (571)-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maria B Marvich, PhD
Examiner
Art Unit 1636

May 3, 2005



JAMES KETTER
PRIMARY EXAMINER